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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,609	08/04/2000	Takeo Tanaami	000807	2753
7590	02/05/2002		EXAMINER	
Moonray Kojima Box 627 Williamstown, MA 01267			FORMAN, BETTY J	
		ART UNIT	PAPER NUMBER	
		1655	6	
		DATE MAILED: 02/05/2002		

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/631,609	TANAAMI, TAKEO
Examiner	Art Unit	
BJ Forman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 17 December 2001.

2a) This action is **FINAL**.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10 and 31-35 is/are pending in the application.

4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 31-35 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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**DETAILED ACTION**

1. This action is in response to papers filed 17 December 2001 in Paper No. 5 in which claims 11-30 were canceled and new claims 31-35 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 4 dated 10 September 2001 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the canceled claims, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Currently claims 31-35 are under prosecution.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-32 are indefinite in Claim 31, line 2, for the recitation "said biomolecules" because the recitation lacks proper antecedent basis in the "micromolecules" recited in lines 1-2. It is suggested that Claim 31 be amended to provide proper antecedent basis e.g. replace "micromolecules" with "biomolecules".

Claims 31-32 are indefinite in Claim 31 because the claim is drawn to a method of producing biochips, but the claim does not recite method steps of biochip production. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of

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precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6. It is suggested that Claim 31 be amended to recite positive and active method steps e.g. amplifying; applying voltage and depositing to thereby produce an array.

Claim 32 is indefinite for the recitation "wherein said polymerase chain reaction is preformed" because the recitation lacks proper antecedent basis in Claim 31 which states that the DNA is amplified within the capillary array, but does not recite a method step of polymerase chain reaction. It is suggested that Claim 31 be amended to provide proper antecedent basis for Claim 32 e.g. recite an active method step of amplification.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch U.S. Patent No. 6,083,763, issued 4 July 2000) in view of Haff et al. (U.S. Patent No. 5,720,923, issued 24 February 1998).

Regarding Claims 31 and 32, Balch teaches a method for producing biochip by depositing micromolecules in arrays on a substrate, wherein said biomolecules are deposited onto sites on the substrate using a capillary array comprising a plurality of capillaries arranged at the same spacing interval as that of sites on said substrate (Column 12, lines 13-29 and Claim 1) wherein said biomolecules are contained with said capillary and are DNA which is

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amplified i.e. PCR product is deposited onto the substrate (Column 35, lines 12-19 and Fig. 14) and wherein the biomolecules are deposited by applying a voltage across said capillary array i.e. electro-osmotic and/or electrophoretic force (Column 15, lines 48-50) but they do not teach DNA contained within said capillary array is amplified within said capillaries by polymerase chain reaction. Haff et al. teach a similar method for producing an array of biomolecules wherein the biomolecules are deposited using a capillary array comprising a plurality of capillaries arranged in the same spacing interval as that of sites on the array and wherein the DNA within the capillary array is amplified within said capillaries by polymerase chain reaction (Column 4, lines 19-35 and Fig. 20) wherein the capillaries pass though "heat exchangers" to provide the required atmospheric temperature changes for the polymerase chain reaction (Column 18, lines 34-44 and Fig. 20 #212 and #213). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the PCR amplification of the DNA in the method of Balch by amplifying the DNA within their capillaries (Claims 31) by changing atmospheric temperature surrounding each capillary (Claim 32) to thereby very rapidly change the temperature of the capillary and PCR reaction within the capillary to greatly reduce the time required for the PCR reaction as taught by Haff et al. (Column 5, lines 27-33) for the obvious benefits of economy time and labor.

Regarding Claims 33-35, Balch teaches the apparatus for producing biochips comprising: capillary holder means for supporting a plurality of capillaries arranged at a same spacing interval as that of sites on a biochip (i.e. capillary sleeve/array template, Column 12, lines 63-67); means for adjusting a gap formed between said capillary holder means and said substrate i.e. print head and positioning device (Column 15, lines 26-37 and Claim 7); means for transferring biomolecules from said capillaries to said substrate said means comprising voltage source means for applying voltage across said capillary holder means e.g. electro-osmotic or electrophoretic force (Column 15, lines 44-52 and Claims 15, 18 and 19); and means for positioning said substrate above or below said capillaries i.e. print head and

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positioning device (Column 15, lines 26-37 and Claim 7). Additionally, Balch teach a PCR product is deposited onto the substrate (Column 35, lines 12-19 and Fig. 14) but they do not teach their apparatus comprises means for amplifying DNA in said capillaries by polymerase chain reaction. Haff et al. teach a similar apparatus for producing an array of biomolecules comprising a holder means for supporting a plurality of capillaries arranged in the same spacing interval as that of sites on the array (i.e. clamp bar, Fig. 20 # 234); means for adjusting a gap formed between said capillary holder and substrate (i.e. tube lift assembly, Fig 20, # 236); and means for transferring biomolecules from said capillaries to said substrate (i.e. plungers, Fig. 20 #266) and further comprising means for amplifying DNA in said capillaries by PCR (Column 4, lines 19-35 and Fig. 20) wherein the capillary PCR simplifies the PCR reaction by reducing thermal gradient problems and shortens the PCR reaction time by providing for very rapid temperature changes (Column 5, lines 11-16 and 28-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the apparatus comprising capillary sleeve/array template through which the capillaries are spatially arrayed and controlled in the method of Balch (Column 12, lines 63-67) by incorporating a heat exchanging capillary sleeve/array template as taught by Haff et al. which also arrays and controls the capillaries but additionally provides the environment for amplifying DNA in the capillary by PCR to thereby provide and deposit PCR products rapidly and accurately as taught by Haff et al. (Column 5, lines 7-35) for the expected benefit of making continuous the amplification and deposition of the biomolecules into a single unified apparatus. The courts have stated that continuous operation of multiple process steps is obvious in view of the prior art teaching of the batch process (see *In re Dilnot*, 319 F.2d 188, 138 USPQ 248 (CCPA 1963 and MPEP, 2144.04 E.).

### **Response to Arguments**

6. Applicant's arguments regarding the previous rejections under 35 U.S.C. 102(b) have been considered but are deemed moot in view of the canceled claims, withdrawn rejections and new grounds for rejection.

Applicant's arguments regarding the previous rejections under 35 U.S.C. 103 have also been considered but are deemed moot in view of the canceled claims, withdrawn rejections and new grounds for rejection. However, the arguments have been addressed as they apply to the above rejections.

Applicant argues that Haff does not deposit micromolecules on site of a substrate. The argument is not found persuasive because as Applicant notes (page 2, third paragraph), Haff deposits micro molecule onto a microtiter tray. The instant claims are drawn to biomolecules deposited onto a substrate which, given the broadest reasonable interpretation, encompasses the microtiter tray of Hall.

Applicant argues that the electro-osmotic or electrophoretic force of Balch cannot deposit very small amount of probe. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., amount of probe deposited and swelling of the droplets) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### **Conclusion**

8. No claim is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.  
Patent Examiner  
Art Unit: 1655  
February 4, 2002

